1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclox DC Xtra Intramammary Suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5.4 g syringe contains:

Active substance:

600 mg Cloxacillin

Excipients:

Qualitative composition of excipients and other constituents
Aluminium Stearate
Liquid Paraffin

An oily off-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dairy cows and heifers.

3.2 Indications for use for each target species

The veterinary medicinal product is formulated for use in cows at the point of drying off, that is, immediately after the last milking of the lactation in order to treat existing mastitis and to provide protection against further infections during the dry period.

The veterinary medicinal product is a useful aid in reducing the incidence of summer mastitis in dry cows at risk.

The veterinary medicinal product is active against Gram-positive organisms which are associated with mastitis. These include *Streptococcus agalactiae* and other *Streptococcus* species, penicillin resistant and sensitive Staphylococci, *Corynebacterium pyogenes*.

The veterinary medicinal product is formulated with a long-acting base and maintains effective antibacterial levels in the majority of quarters in dry cows for at least 7 weeks.

3.3 Contraindications

Do not use on cows which have a short dry period. Not intended for use within 42 days of calving.

Animals must not be slaughtered for human consumption during treatment.

Do not use in the treatment of lactating cows. Should this occur, milk should be discarded for 42 days, following which time milk should be tested until the levels of antibiotic are below the EU maximum residue limit of 30 µg/kg for cloxacillin.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

When infusing heifers it is important that the syringe nozzle is not introduced into the teat.

The recommended procedure is as follows:
The animal(s) should be properly restrained. The teats are cleaned and disinfected. The teat orifice is located and the nozzle of the syringe placed against it but NOT inserted. When the syringe plunger is depressed the antibiotic passes easily through the teat into the udder.

In cows suffering from hypocalcaemia it may be necessary to withhold milk for a longer period. In such cases milk should be withheld until the levels of antibiotic are below the maximum acceptable residue level i.e. 0.03 µg/ml for cloxacillin.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Protective gloves should always be worn when infusing heifers, to avoid skin contact with the product (see warning on hypersensitivity below).

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reaction to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy.
Do not use in lactating cows.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For intramammary infusion in dairy cows and heifers.

Dry Off Therapy: After the final milking of a lactation, clean and disinfect the teats and introduce the contents of one tube into each quarter via the teat canal.

Summer Mastitis Therapy: In heifers, prior to the first calving and in adult cows, at risk to summer mastitis, clean and disinfect the teats and introduce the contents of one syringe into each quarter.

The syringe may only be used once. Part used syringes must be discarded.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days.
Milk: 96 hours.

Not for use in cows with dry periods of less than 42 days. If calving occurs before 42 days, milk must only be taken from 42 days plus 96 hours after the last treatment.

Animals must not be slaughtered for human consumption during treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ51CFO2

4.2 Pharmacodynamics

Cloxacillin is a beta-lactam antibiotic and its structure contains the beta-lactam ring and thiazolidine ring common to all penicillins.

Cloxacillin is relatively resistant to staphylococcal beta-lactamases but of lower activity than penicillin G against susceptible Gram-positive bacteria and inactive against Gram-negative bacteria.

Beta-lactam antibiotics prevent the bacterial cell wall from forming by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes, which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action but cause lysis only of growing cells.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Store below 25 °C.

5.4 Nature and composition of immediate packaging

Cartons of 24 and 120 syringes.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/043/001

8. DATE OF FIRST AUTHORISATION

15/05/1996

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10/04/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).